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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,285	03/08/2001	Dongfang Liu	M0656/7063(HCL)	6877

7590

04/23/2002

Helen C. Lockhart
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Boston, MA 02210

EXAMINER

SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/802,285

Applicant(s)

LIU ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 02 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 18, 20, 23, 27, 28, 32-36, 50 and 55-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-12, 18, 20, 23, 27, 28, 32-36, 50, and 55-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 23, 27, 28, and 32-35 drawn to heparinase III and derivatives of, classified in class 435 subclass 232. (Lyase; EC 4.2.2.8)
- II. Claims 1-12, drawn to treatments with heparinase III and derivatives of, classified in class 424 subclass 94.5.
- III. Claim 55, drawn to preparation of LMWH with heparinase III, classified in class 435, subclass 84.
- IV. Claim 56, drawn to LMWH, classified in class 536 subclass 21.
- V. Claims 57-60, drawn to treatments with LMWH, classified in class 514 subclass 56.
- VI. Claim 18, drawn to method of making HLGAG fragments from a tumor by treating said tumor with heparinase III, classified in class 435, subclass 84.
- VII. Claim 36, drawn to method of cleaving a heparin-like glycosaminoglycan with heparinase III, classified in class 435 subclass 84.
- VIII. Claims 23 and 27, drawn to compositions of HLGAG fragments, classified in class 537 subclass 21.
- IX. Claims 20 and 50, drawn to treatment with HLGAG fragments, classified in class 514 subclass 56.

The inventions are distinct, each from the other because:

I v II Heparinase v treatments with heparinase

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Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case heparinase can also be used for cleavage of heparin and its derivatives.

I v III Heparinase v preparation of LMWH with heparinase

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case heparinase can also be used as a pharmaceutical agent.

I v IV and VIII Heparinase v LMWH and compositions of HLGAG fragments

The heparinase of Invention I unrelated to the LMWH and compositions of HLGAG fragments, Invention IV and VIII, respectively. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, products of Inventions I, IV, and VIII are different inventions because they are physically and functionally distinct chemical entities

I v V and IX Heparinase v treatments with LMWH and treatment with HLGAG fragments

Invention I is unrelated to Inventions V and IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Inventions V and IX can neither use the product of invention I nor make the product of Invention I.

I v VI Heparinase v method of making HLGAG fragments from a tumor

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case heparinase can also be used as a pharmaceutical agent.

I v VII Heparinase v method of cleaving a heparin-like glycosaminoglycan with heparinase

Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case heparinase can also be used as a pharmaceutical agent.

I v VIII Heparinase v compositions of HLGAG fragments

The heparinase of Invention I is related to the HLGAG fragments of Invention VIII by virtue of being an enzyme which can produce HLGAG fragments. Although the enzyme and compound are related since the heparinase can generate HLGAG fragments from heparin, they

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are distinct inventions because they are physically and functionally distinct chemical entities, and the HLGAG fragments product can be made by another and materially different process, such as by chemical synthesis or purification from the natural source. Further, the heparinase may be used for processes other than the production of the LMWH, such as in a pharmaceutical composition.

II v III, VI, and VII Treatments with heparinase v preparation of LMWH with heparinase, method of making HLGAG fragments from a tumor, and method of cleaving a heparin-like glycosaminoglycan with heparinase

Invention II is unrelated to Inventions III, VI, and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods of Invention II are independent from the methods of Inventions III, VI, and VII as methods of Invention II comprise different steps, utilize different products and produce different results.

II v IV and VIII Treatments with heparinase v LMWH and compositions of HLGAG fragments

Invention II unrelated to Inventions IV and VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of Invention II can neither use the products of invention IV and VIII nor be used to make said products.

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II v V and IX Treatments with heparinase v treatments with LMWH and treatment with HLGAG fragments

Invention II is unrelated to Inventions V and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant cases, the methods of Inventions II comprise different steps and utilize different products from the methods of Inventions V and IX

III v IV Preparation of LMWH with heparinase v LMWH

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case LMWH can also be made by chemical synthesis or by isolation from a native source.

III v V, VI, and IX Preparation of LMWH with heparinase v treatments with LMWH, method of making HLGAG fragments from a tumor, and treatment with HLGAG fragments

Invention III is unrelated to Inventions V, VI, and IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods of Inventions III are independent from the methods of Inventions V, VI, and IX as the methods of Inventions III comprise different steps, utilize different products and produce different results.

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III v VII Preparation of LMWH with heparinase v method of cleaving a heparin-like glycosaminoglycan with heparinase

Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods of Inventions III and VII are independent as they utilize different products and produce different results.

III v VIII Preparation of LMWH with heparinase v compositions of HLGAG fragments

Inventions III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of invention III can neither use the product of invention VIII nor be used to make the product of invention VIII.

IV v V LMWH v treatments with LMWH

Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using LMWH can also be practiced with modified heparinase III molecules.

IV v VI, VII, and IX LMWH v method of making HLGAG fragments from a tumor, method of cleaving a heparin-like glycosaminoglycan with heparinase, and treatment with HLGAG fragments

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The product of Invention IV and the methods of Inventions VI, VII, and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of Inventions VI, VII, and IX are distinct from the product of Invention IV wherein the methods of Invention VI, VII, and IX can neither utilize the product of Invention IV nor be used to make said product.

IV v VIII LMWH v compositions of HLGAG fragments

Inventions IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case they are different inventions because they are physically and functionally distinct chemical entities.

V v VI and VII Treatments with LMWH v method of making HLGAG fragments from a tumor and method of cleaving a heparin-like glycosaminoglycan with heparinase

Invention V is unrelated to Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods of Inventions V are independent from the methods of Inventions VI and VII as the methods of Inventions V comprise different steps, utilize different products and produce different results.

V v VIII Treatments with LMWH v compositions of HLGAG fragments

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Inventions V and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of invention V can neither use the product of invention VIII nor be used to make said product.

V v IX Treatments with LMWH v treatment with HLGAG fragments

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods of Inventions IV and VI are independent as they comprise different steps and utilize different products.

VI v VII Method of making HLGAG fragments from a tumor v method of cleaving a heparin-like glycosaminoglycan with heparinase

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods of Inventions VI and VII are independent as they comprise different steps and utilize different products.

VI v VIII Method of making HLGAG fragments from a tumor v compositions of HLGAG fragments

Inventions VI and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the

instant case the product of Invention VIII can also be made by chemically cleaving the isolated and purified starting material or by chemical synthesis.

VI v IX Method of making HLGAG fragments from a tumor v treatment with HLGAG fragments

Inventions VI and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods of Inventions VI and IX are independent as they comprise different steps, utilize different products and produce different results.

VII v VIII Method of cleaving a heparin-like glycosaminoglycan with heparinase v compositions of HLGAG fragments

Inventions VII and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention VIII can be made by isolation from native tissues or treatment of native tissue with heparinase III.

VII v IX Method of cleaving a heparin-like glycosaminoglycan with heparinase v treatment with HLGAG fragments

Inventions VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods of Inventions VII

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and IX are independent as they comprise different steps, utilize different products and produce different results.

VIII v IX Compositions of HLGAG fragments v treatment with HLGAG fragments

Inventions VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using HLGAG fragments can also be practiced with HLGAG degrading enzymes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Helen Lockhart on April 12, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

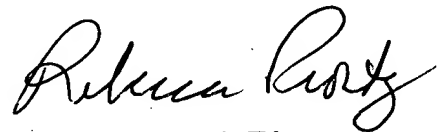
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800

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